
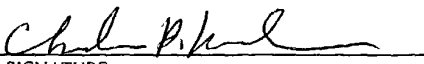


02 \UC07 Rec'd PCT/PTO 12 FEB 2002 CT

FORM PTO-1190 (REV 11-98)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER	
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371				146.1381	
				U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/049874	
INTERNATIONAL APPLICATION NO PCT/FR00/02393		INTERNATIONAL FILING DATE August 28, 2000		PRIORITY DATE CLAIMED August 26, 1999	
TITLE OF INVENTION SPHERICAL AGGLOMERATES OF TELITHROMYCTIN, THEIR PREPARATION PROCESS AND THEIR USE IN THE PREPARATION OF PHARMACEUTICAL FORMS					
APPLICANT(S) FOR DO/EO/US GODARD et al					
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information					
<p>1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371</p> <p>3. <input checked="" type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).</p> <p>4. <input type="checkbox"/> A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p> a. <input checked="" type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau).</p> <p> b. <input type="checkbox"/> has been transmitted by the International Bureau.</p> <p> c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input checked="" type="checkbox"/> A translation of the International Application into English (35 U.S.C. 371(c)(2)).</p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p> a. <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau).</p> <p> b. <input type="checkbox"/> have been transmitted by the International Bureau.</p> <p> c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p> d. <input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). Unexecuted</p> <p>10. <input checked="" type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5))</p> <p>Items 11. to 16. below concern document(s) or information included:</p> <p>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input checked="" type="checkbox"/> A FIRST preliminary amendment.</p> <p> <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment.</p> <p>14. <input type="checkbox"/> A substitute specification.</p> <p>15. <input type="checkbox"/> A change of power of attorney and/or address letter.</p> <p>16. <input checked="" type="checkbox"/> Other items or information: Amended Pages 3, 4, 5, 6 and 7; PCT/IB/306</p>					

U.S. APPLICATION NO. 10/049874

INTERNATIONAL APPLICATION NO.
PCT/FR00/02393JC11 Rec'd PCT/PTO 12 FEB 2002
146.1381

				CALCULATIONS PTO USE ONLY	
21. <input checked="" type="checkbox"/> The following fees are submitted: BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)): Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO..... \$1000.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$860.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$710.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$690.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00 ENTER APPROPRIATE BASIC FEE AMOUNT =				\$ 1040.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	- 20 =		x \$18.00	\$	
Independent claims	- 3 =		x \$80.00	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$270.00	\$	
TOTAL OF ABOVE CALCULATIONS =				\$ 1040.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				+	
SUBTOTAL =				\$ 1040.00	
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	
TOTAL NATIONAL FEE =				\$ 1040.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.3 b). \$40.00 per property +				\$	
TOTAL FEES ENCLOSED =				\$ 1040.00	
				Amount to be refunded:	\$
				charged:	\$
a. <input checked="" type="checkbox"/> PTO form 2038 for \$1040.00 is enclosed. A check in the amount of \$ _____ to cover the above fees is enclosed.					
b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.					
c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>02-2275</u> . A duplicate copy of this sheet is enclosed.					
d. <input checked="" type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.					
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO: Bierman, Muserlian and Lucas 600 Third Avenue New York, NY 10016					
					
			20311 PATENT TRADEMARK OFFICE	SIGNATURE Charles A. Muserlian NAME 19,683 REGISTRATION NUMBER	

JC11 Rec'd PCT/PTO 12 FEB 2002

Our Ref.: 146.1381

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	:
GODARD et al	:
PCT/FR00/02393	: PCT Date: August 28, 2000
Serial No.:	:
Filed: Concurrently Herewith	:
For: SPHERICAL...PHARMACEUTICAL	:
FORMS	:
	600 Third Avenue
	New York, NY 10016
	February 11, 2002

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Please amend this application as follows:

IN THE SPECIFICATION:

Page 1, before line 1, insert

--This application is a 371 of PCT/FR00/02393 filed
August 28, 2000.--

IN THE CLAIMS:

Claim 2 (amended) A spherical agglomerate of telithromycin
of claim 1, wherein the size of the particles is between 30 and 400
microns.

Claim 3 (amended) A spherical agglomerate of telithromycin of claim 2, wherein the median size of the particles is between 80 and 150 microns.

Claim 4 (amended) A spherical agglomerate of telithromycin of claim 1, wherein the median size of the particles is about 100 microns.

Claim 5 (amended) A process for the preparation of agglomerates of claim 1, comprising preparing a suspension of telithromycin crystals, and coating the crystals with a phase insoluble in telithromycin from which telithromycin progressively crystallizes.

Claim 6 (amended) The process of claim 5, wherein a solution of telithromycin in acetone is used.

Claim 7 (amended) The process of claim 5, wherein the crystallization takes place in an acetone/isopropyl ether mixture.

Claim 8 (amended) The process of claim 5, wherein the crystallization is carried out between -5°C and -15°C.

Cancel claims 9 to 13 and add the following claims.

--14. A spherical agglomerate of claim 1 micro-encapsulated in


at least one polymer.

15. A method of treating bacterial infections in humans comprising administering to humans in need thereof an antibactericidally effective amount of a composition of claim 10.--

REMARKS

The amendment is submitted to refer to the PCT application, to remove multiple dependency from the claims and to conform the claims to the American practice.

Respectfully submitted,
BIERMAN, MUSERLIAN AND LUCAS


Charles A. Muserlian, #19,683
Attorney for Applicant(s)
Tel. # (212) 661-8000

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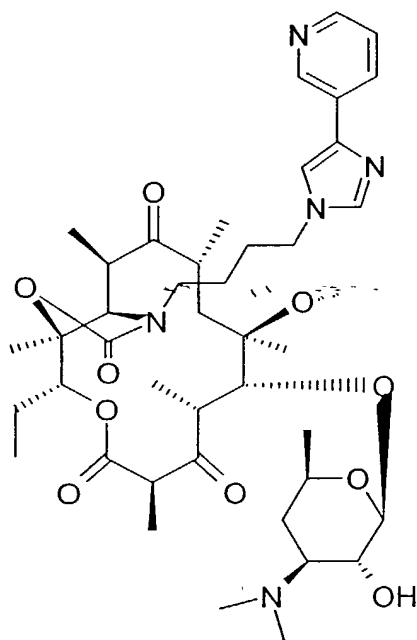
Enclosures: Marked-Up Version of Specification and Claims
Return Receipt Postcard

Spherical agglomerates of telithromycin, their preparation process and their use in the preparation of pharmaceutical forms.

--This application is a 371 of PCT/FR00/02393 filed August 28, 2000.--

A subject of the present invention is spherical
5 agglomerates of telithromycin, their preparation process and their use in the preparation of pharmaceutical forms.

Telithromycin or 11,12-dideoxy-3-de((2,6-dideoxy-3-C-methyl-3-O-methyl-alpha-L-ribohexopyranosyl)oxy)-6-O-methyl-3-oxo-12,11-(oxycarbonyl((4-(4-(3-pyridinyl)-1H-imidazol-1-yl)butyl)imino))-erythromycin is a product endowed with
10 antibiotic properties of structure: ..



described and claimed in European Patent 680967.

30 The oral route is a preferred form of administration for this product. Some patients, children in particular, have difficulty in swallowing tablets and capsules and therefore it is desirable to have available other forms of administration such as for example oral suspensions, ready to
35 use or prepared extemporaneously at the time of use.

CONFIRMATION COPY

CLAIMS

- 1) Spherical agglomerates of telithromycin.
- 2) ~~A~~ ^{of} Spherical agglomerates of telithromycin according to
5 claim 1, ^{wherein} ~~characterized in that~~ the size of the particles is
between 30 and 400 microns. ^{of}
- 3) ~~A~~ ^{of} Spherical agglomerates of telithromycin according to
claim 2, ^{wherein} ~~characterized in that~~ the median size of the
particles is ~~situated~~ between 80 and 150 microns. ^{of claim 4}
- 10 4) ~~A~~ ^{of} Spherical agglomerates of telithromycin according to any
one of claims 1 to 3, ^{wherein} ~~characterized in that~~ the median size
of the particles is ^{about} ~~situated towards~~ 100 microns. ^{of}
- 5) ~~A~~ ^{of} Process for the preparation of agglomerates according to
any one of claims 1 to 4, ^{claim 1, comprising preparing} ~~characterized in that~~ a suspension
15 of telithromycin crystals is ^{coating} ~~prepared~~, and ~~these~~ ^{from} crystals are
then ~~coated~~ with a phase insoluble in telithromycin, ^{telithromycin} which progressively crystallizes.
- 6) ~~The~~ ^{of} ~~Preparation~~ process according to claim 5, ^{wherein} ~~characterized~~
~~in that~~ a solution of telithromycin in acetone is used.
- 20 7) ~~The~~ ^{of} ~~Preparation~~ process according to claim 5 ~~or 6~~,
^{wherein} ~~characterized in that~~ the crystallization takes place in an
acetone/isopropyl ether mixture.
- 8) ~~The~~ ^{of} ~~Preparation~~ process according to any one of claims 5 to
~~7~~, ^{wherein} ~~characterized in that~~ the crystallization is carried out
25 between -5°C and -15°C.
- 9) Spherical agglomerates of telithromycin as obtained by
the process according to any one of claims 5 to 8.
- 10) Spherical agglomerates of telithromycin according to
claim 9, characterized in that the particle size is comprised
30 between 30 and 400 microns.
- 11) Spherical agglomerates of telithromycin according to claim
10, characterized in that the median size of the particles is
situated between 80 and 150 microns.

12) Spherical agglomerates of telithromycin according to any one of claims 9 to 11, characterized in that the median size of the particles is situated towards 100 microns.

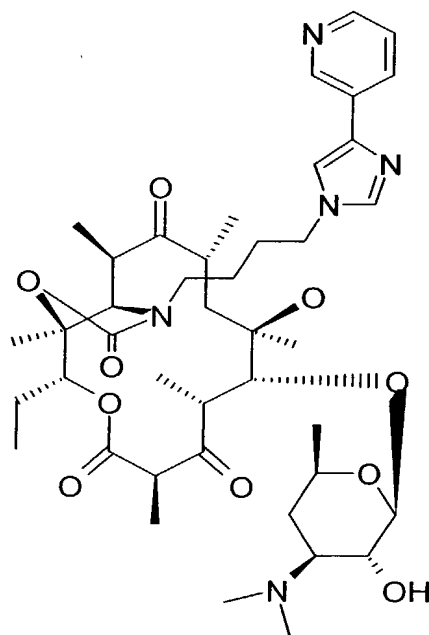
13) Use of the spherical agglomerates according to any one
5 of claims 1 to 4 and 9 to 12, characterized in that the spherical agglomerates are surrounded by a layer of polymer in order to obtain the sought galenical form.

1

Spherical agglomerates of telithromycin, their preparation process and their use in the preparation of pharmaceutical forms.

A subject of the present invention is spherical agglomerates of telithromycin, their preparation process and their use in the preparation of pharmaceutical forms.

Telithromycin or 11,12-dideoxy-3-de((2,6-dideoxy-3-C-methyl-3-O-methyl-alpha-L-ribohexopyranosyl)oxy)-6-O-methyl-3-oxo-12,11-(oxycarbonyl((4-(4-(3-pyridinyl)-1H-imidazol-1-yl)butyl)imino))-erythromycin is a product endowed with antibiotic properties of structure:



described and claimed in European Patent 680967.

The oral route is a preferred form of administration for this product. Some patients, children in particular, have difficulty in swallowing tablets and capsules and therefore it is desirable to have available other forms of administration such as for example oral suspensions, ready to use or prepared extemporaneously at the time of use.

CONFIRMATION COPY

Telithromycin is an active ingredient which has an unpleasant taste. Galenical forms must therefore be produced which mask the taste of the product yet preserve a good bioavailability.

5 The physico-chemical properties of telithromycin are such that they permit micro-encapsulation, i.e the coating of the active ingredient with a polymer or a mixture of polymers.

10 The micro-encapsulation can be carried out by spraying a polymer or by interfacial polymerization or by coacervation. In order to obtain a good micro-encapsulation, spherical particles of active ingredient must be available, particles which are neither too small, to prevent them from agglomerating among themselves, nor too large, in order that
15 the dissolution is not too slow, and the particles must be spherical so that the covering of the active ingredient by the polymer is correct and in order to obtain good release kinetics for the active ingredient.

20 A subject of the invention is spherical agglomerates of telithromycin.

 The spherical agglomerates are obtained as shown below by direct transformation of the crystals into masses of spherical shape.

25 As regards spherical agglomerates in general, reference may be had to the article by Frederica Guillaume and Anne-Marie Guyot-Hermann in Il Farmaco XLVIII 1993 pages 473 et seq.

30 The agglomerates of the invention permit a good micro-encapsulation and a subject of the invention is in particular the use characterized in that the spherical agglomerates are surrounded by a layer of polymer in order to obtain the sought galenical form, for example micro-capsules.

A subject of the invention is spherical agglomerates of telithromycin characterized in that the size of the particles is between 30 and 400 microns.

A quite particular subject of the invention is spherical
5 agglomerates of telithromycin characterized in that the median size of the particles is situated between 80 and 150 microns and in particular spherical agglomerates of telithromycin characterized in that the median size of the
10 particles is situated towards 100 microns, i.e. characterized in that half of the agglomerates are less than 100 microns in size.

A subject of the invention is also a process for the preparation of spherical agglomerates characterized in that a suspension of telithromycin crystals is prepared, and these
15 crystals are then coated with a phase insoluble in telithromycin which progressively crystallizes.

A subject of the invention is in particular a preparation process characterized in that a solution of telithromycin in acetone is used.

20 A more particular subject of the invention is a preparation process characterized in that the crystallization takes place in an acetone/isopropyl ether mixture.

In a preferred embodiment, the crystallization is carried out between -5 and -15°C. The size of the spherical
25 agglomerates is controlled by adjusting the stirring speed.

Finally a subject of the invention is spherical agglomerates of telithromycin as obtained by the preparation process described above.

The following example illustrates the invention without, however, limiting it.
30

EXAMPLE:

a) Preparation of the acetone solution

The following are introduced under nitrogen:

- telithromycin 64 g
- anhydrous pure acetone 128 ml

Stirring is carried out under a slight nitrogen overpressure between 19°C and 21°C and a check is carried out to ensure that the dissolution is total.

If necessary, the quantity of water is added to obtain a 2.9% product, adding:

- demineralized water 0.26 ml.

b) Crystallization

The following are introduced under nitrogen, into a double-casing reactor fitted with a mechanical stirrer, a thermometric probe and a nitrogen inlet:

- isopropyl ether 640 ml
- anhydrous pure acetone 12.8 ml

The temperature is stabilized between 19°C and 21°C.

5% by mass of the acetone solution is introduced, while stirring at 350 rpm.

Then, while still stirring at 350 rpm, the crystallization is initiated with 0.96 g of micronized telithromycin suspended by sonication in:

- isopropyl ether 3.2 ml

Crystallization develops immediately after initiation.

Stirring is carried out for 15 minutes at 20±1°C then the suspension is cooled down to -10±1°C over 30 minutes.

The rest of the acetone solution is introduced:

- acetone solution of telithromycin 157.2 g

Stirring is carried out for another 1 hour at -10°C.

c) Isolation

Thorough drying and washing by clarifications are carried out twice with, each time:

- isopropyl ether 64 ml.

Drying is carried out in an oven at 40°C under vacuum, followed by sieving on a 500 µm grid.

50.4 g of spherical agglomerates of telithromycin are obtained.

Granulometry

The size of the particles is determined by laser
5 diffraction using a HELOS SYMPATEC® model granulometer.

The results obtained are the following:

10% of the particles have a diameter of < 77 microns

50% of the particles have a diameter of < 107 microns

90% of the particles have a diameter of < 166 microns.

10 Figure 1 represents agglomerates obtained by operating as shown above, the scale being

1 cm = 150 microns.

Use

The product of the example was used to prepare, by
15 simple coacervation or by direct spraying of a suitable polymer, micro-capsules intended for the preparation of oral suspensions to be prepared extemporaneously.

The prepared suspensions are accepted by children and retain good release kinetics.

20

CLAIMS

- 1) Spherical agglomerates of telithromycin.
- 2) Spherical agglomerates of telithromycin according to
5 claim 1, characterized in that the size of the particles is
between 30 and 400 microns.
- 3) Spherical agglomerates of telithromycin according to
claim 2, characterized in that the median size of the
particles is situated between 80 and 150 microns.
- 10 4) Spherical agglomerates of telithromycin according to any
one of claims 1 to 3, characterized in that the median size
of the particles is situated towards 100 microns.
- 5) Process for the preparation of agglomerates according to
any one of claims 1 to 4, characterized in that a suspension
15 of telithromycin crystals is prepared, and these crystals are
then coated with a phase insoluble in telithromycin which
progressively crystallizes.
- 6) Preparation process according to claim 5, characterized
in that a solution of telithromycin in acetone is used.
- 20 7) Preparation process according to claim 5 or 6,
characterized in that the crystallization takes place in an
acetone/isopropyl ether mixture.
- 8) Preparation process according to any one of claims 5 to
7, characterized in that the crystallization is carried out
25 between -5°C and -15°C.
- 9) Spherical agglomerates of telithromycin as obtained by
the process according to any one of claims 5 to 8.
- 10) Spherical agglomerates of telithromycin according to
claim 9, characterized in that the particle size is comprised
30 between 30 and 400 microns.
- 11) Spherical agglomerates of telithromycin according to claim
10, characterized in that the median size of the particles is
situated between 80 and 150 microns.

(12) DEMANDE INTERNATIONALE PUBLIÉE EN VERTU DU TRAITÉ DE COOPÉRATION
EN MATIÈRE DE BREVETS (PCT)

(19) Organisation Mondiale de la Propriété
Intellectuelle
Bureau international



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1 mars 2001 (01.03.2001)

PCT

(10) Numéro de publication internationale
WO 01/14393 A2

- (51) Classification internationale des brevets⁷: C07H, A61K / (74) Mandataire: VIEILLEFOSSE, Jean, Claude Aventis Pharma S.A.; Département des Brevets, 102, route de Noisy, F-93235 Romainville Cedex (FR).
- (21) Numéro de la demande internationale: PCT/FR00/02393 (81) États désignés (*national*): AE, AG, AL, AU, BA, BB, BG, BR, BZ, CA, CN, CR, CU, CZ, DM, DZ, EE, GD, GE, HR, HU, ID, IL, IN, IS, JP, KP, KR, LC, LK, LR, LT, LV, MA, MG, MK, MN, MX, NO, NZ, PL, RO, SG, SI, SK, TR, TT, UA, US, UZ, VN, YU, ZA.
- (22) Date de dépôt international: 28 août 2000 (28.08.2000)
- (25) Langue de dépôt: français
- (26) Langue de publication: français (84) États désignés (*régional*): brevet ARIPO (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), brevet eurasien (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), brevet européen (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), brevet OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- (30) Données relatives à la priorité: 99/10810 26 août 1999 (26.08.1999) FR
- (71) Déposant (*pour tous les États désignés sauf US*): AVENTIS PHARMA S.A. [FR/FR]; 20, avenue Raymond Aron, F-92160 Antony (FR).
- (72) Inventeurs; et
- (75) Inventeurs/Déposants (*pour US seulement*): GODARD, Jean-Yves [FR/FR]; 1A, place des Fêtes, F-93340 Le Raincy (FR). ROGNON, Valérie [FR/FR]; 5, rue des Fougères, F-93470 Coubron (FR).
- Publiée:
— Sans rapport de recherche internationale, sera republiée dès réception de ce rapport.
- En ce qui concerne les codes à deux lettres et autres abréviations, se référer aux "Notes explicatives relatives aux codes et abréviations" figurant au début de chaque numéro ordinaire de la Gazette du PCT.

(54) Title: SPHERICAL TELITHROMYCIN CLUSTERS, METHOD FOR THE PRODUCTION AND USE THEREOF IN THE PREPARATION OF PHARMACEUTICAL FORMS

(54) Titre: AGGLOMERATS SPHERIQUES DE TELITHROMYCINE, LEUR PROCÉDE DE PREPARATION ET LEUR APPLICATION DANS LA PREPARATION DE FORMES PHARMACEUTIQUES

(57) Abstract: The invention relates to spherical telithromycin clusters and to a method for the production thereof characterized in that a telithromycin crystal suspension is prepared, said crystals are coated with a telithromycin insoluble phase which gradually crystallizes. The spherical telithromycin clusters are used in the preparation of micro-capsules.

(57) Abrégé: L'invention a pour objet les agglomérats sphériques de télithromycine. L'invention a pour objet un procédé caractérisé en ce que l'on prépare une suspension de cristaux de télithromycine, puis enrobe ces cristaux d'une phase insoluble en télithromycine qui cristallise progressivement. Les agglomérats sphériques de l'invention trouvent leur application dans la préparation de micro capsules.

WO 01/14393 A2

Please type a plus sign (+) inside this box →



PTO/SB-01 (8-95)

Approved for use through 9/30/98 OMB 0651-0032
Patent and Trademark Office U.S. DEPARTMENT OF COMMERCE

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION

Declaration ☒ OR
Submitted
with Initial Filing

Declaration ☐
Submitted after
Initial Filing

Attorney Docket Number

146.1381

First Named Inventor

GODARD et al

COMPLETE IF KNOWN

Application Number

PCT/FR00/02393

Filing Date

August 28, 2000

Group Art Unit

Examiner Name

RECEIVED
APR 23 2002
TECH CENTER 1800/2900

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SPHERICAL AGGLOMERATES OF TELITHROMYCIN, THEIR PREPARATION PROCESS AND
THEIR USE IN THE PREPARATION OF PHARMACEUTICAL FORMS

(Title of the invention)

the specification of which

☐ is attached hereto
OR

☒ was filed on (MM/DD/YYYY)

08/28/00

as United States Application Number or PCT International

Application Number

PCT/FR00/02393

and was amended on (MM/DD/YYYY)

(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37 Code of Federal Regulations, §1.56

I hereby claim foreign priority benefits under Title 35 United States Code §119 (a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
99/10810	France	08/26/99	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority sheet attached hereto

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional application(s) listed below

Application Number(s)	Filing Date (MM/DD/YYYY)	<input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority sheet attached hereto

{Page 1 of 5}

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DECLARATION

I hereby claim the benefit under Title 35, United States Code § 120 of any United States application(s), or § 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application Number	PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)

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☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority sheet attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Name	Registration Number	Name	Registration Number
Bierman, Muserlian and Lucas	18,818		
Jordan B. Bierman	18,629		
Charles A. Muserlian	19,683		
Donald C. Lucas	31,275		

☐ Additional registered practitioner(s) named on a supplemental sheet attached hereto.

Direct all correspondence to:

Name	Charles A. Muserlian		
Address	Bierman, Muserlian and Lucas		
Address	600 Third Avenue		
City	New York	State	NY
Country	U.S.A.	Telephone	212-661-8000
		Fax	212-661-8002

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor:

☐ A petition has been filed for this unsigned inventor

Given Name	Jean-Yves	Middle Initial		Family Name	GODARD	Suffix e.g. Jr.	
Inventor's Signature						Date	7.03.2002
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Post Office Address							
City	Le Raincy	State		Zip	F-93340	Country	France

☒ Additional inventors are being named on supplemental sheet(s) attached hereto

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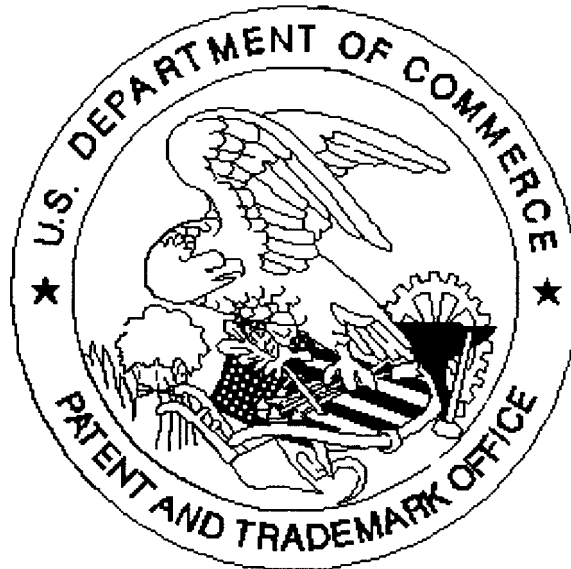
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DECLARATION	ADDITIONAL INVENTOR(S) Supplemental Sheet
--------------------	--

Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name	Valerie	Middle Initial		Family Name	ROGNON-RAVAUX	Suffix e.g. Jr.	
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Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name		Middle Initial		Family Name		Suffix e.g. Jr.	
Inventor's Signature					Date		
Residence: City		State		Country		Citizenship	
Post Office Address							
Post Office Address							
City		State		Zip		Country	
Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name		Middle Initial		Family Name		Suffix e.g. Jr.	
Inventor's Signature					Date		
Residence: City		State		Country		Citizenship	
Post Office Address							
Post Office Address							
City		State		Zip		Country	
Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name		Middle Initial		Family Name		Suffix e.g. Jr.	
Inventor's Signature					Date		
Residence: City		State		Country		Citizenship	
Post Office Address							
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